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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,766	06/28/2000	George W. Hawkins	99,215-A	5882

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AMERSHAM BIOSCIENCES
PATENT DEPARTMENT
800 CENTENNIAL AVENUE
PISCATAWAY, NJ 08855

EXAMINER

CALAMITA, HEATHER

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SA/4

Office Action Summary	Application No.		Applicant(s)	
	09/605,766		HAWKINS, GEORGE W.	
	Examiner		Art Unit	
	Heather G. Calamita, Ph.D.		1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,36,38-60 and 64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,36,38-60 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed 24 May 2004 has been entered and overcomes the double patenting rejection over 09/492013.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 36,37,40,45,47,49 & 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottingham et al. WO 97/10056 20 March 1997).

Cottingham et al. teach an apparatus for performing biological reactions (see whole doc. esp. abstract & figure 4, DNA amplification and probe assay device) comprising a substrate (see page 13 line 3-4 DNA card with bottom and top layer) and an array with biomolecular probes positioned on first surface (see page 10 lines 1-15 teaching an array arrangement of DNA amplification and assay reagents which includes primers and probes spotted on surface) and flexible layer affixed to first surface by an adhesive layer forming reaction volume (see page 13 lines 9 & 10 adhesive binding a plastic film) and port (see page 13 line 21 & last line air vent and sample port). The ports extend through flexible layer (see Figure 4 detail 28 & 26). They teach apparatus may further comprise measuring instrument and heated carrier (see figure 13 detail 80, 81 and page 21 first full paragraph).

Response to Arguments

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3. With respect to the rejections recited above, applicant's arguments filed 24 May 2004 have been fully considered but they are not persuasive.

Applicant argues Cottingham does not teach or disclose an array of biomolecular probes positioned on the first surface of the substrate, a flexible layer or an adhesive layer. Applicant further argues that Cottingham teaches an apparatus comprising multiple layers which contain a single spot. Applicant states the DNA card taught by Cottingham consists of five distinct layers, as the middle plastic layer is held together with the other two plastic layers by a pressure sensitive adhesive.

In response to applicant's argument, the examiner points out that Cottingham teaches an array arrangement of DNA amplification and assay reagents which include primers and probes spotted on surface (see page 10 lines 1-15). Cottingham, further teaches a flexible layer (a layer of plastic film having a thickness of approximately 0.015 inches or 0.381 millimeters) affixed to first surface by an adhesive layer forming reaction volume (see page 13 lines 7-10) Applicant uses the open language "comprising" in the claims allowing for the presence of additional components of the apparatus in the reference, therefore rendering irrelevant the number of layers present in Cottingham's apparatus. In claiming their invention, applicant states in step c) of claim 1, a flexible layer affixed to said first surface by an adhesive layer; applicant neither claims a specific adhesive nor specific mechanism by which the layers are adhered. Therefore, Cottingham's pressure sensitive adhesive layer satisfies the claim language.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43 & 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al (WO 97/10056 20 March 1997) over Rehman et al. (NAR vol. 27 no. 2 pp. 649-655).

The teachings of Cottingham et al are described previously.

Cottingham do not teach polyacrylamide.

Rehman teach polyacrylamide layer for binding probes (see whole doc. esp. intro).

One of ordinary skill in the art would have been motivated to apply Rehman's polyacrylamide to Cottingham's device in order to immobilize DNA probes at a greater capacity. Rehman et al. state that polyacrylamide provides for great probe capacity, density, lower non-specific binding levels and relatively high thermal stability particularly in amplifications of solid phase PCR and hybridization assays (see intro). It would have been prima facie obvious to apply Rehman's polyacrylamide to Cottingham's device for DNA probe assays in order to increase the hybridization efficiency of the probe reagents.

5. Claims 48,50-56 & 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al. (WO 97/10056 20 March 1997) over Bjornson et al. (W099/19717 22 April 1999)

The teachings of Cottingham et al. are described previously.

Cottingham do not teach flexible layer with polyester, polypropylene.

Bjornson et al. teach a variety of well known flexible films such as plastics, acrylics and polyethylenes of varying widths (see whole doc. esp. page 17 line 15-17). They teach rolling with roller (see figure 5). They teach adhesives (see page 25 line 9).

One of ordinary skill in the art would have been motivated to apply Bjornson's

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teachings of rollers and flexible films to Cottingham's device in order to construct a cover for the reaction and press to ensure a seal of the film. It would have been prima facie obvious to apply Bjornson's teaching of films and roller press in order to ensure a sealed layer in Cottingham's device.

6. Claims 39, 41, 42, 46, 58, 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al. (WO 97/10056 20 March 1997) over Besemer et al. (USPN 5,945,337 August 31, 1999).

The teachings of Cottingham et al. are described previously.

Cottingham do not teach sample chip and heater

Besemer et al. teach a chip device containing a substrate having an array of probes attached to cavity (see whole document esp. col. 1 line 65- col.2 line 3 & claim 1 & 2). The body includes two inlets that allow fluids into and through cavity. A seal, plug or any other seal may be provided for each inlet to retain fluid within cavity (see col. 6 line 39). The body is formed by welding two pieces together. They also teach heaters may be connected to device (col. 9 line 62). They also teach of variety of surface supports including glass, silicon, Ge, GaAs (see col. 4 line 6%).

One of ordinary skill in the art would have been motivated to insert Besemer et al's chips to Cottingham et al's device in order to perform hybridization assays. Array chips were well known and commonly practiced in the art to perform detection assays. It would have been prima facie obvious to apply Besemer et al's chip to Cottingham et al's device in order to perform a plurality of different assays simultaneously.

7. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al. (WO 97/10056 20 March 1997) in view of Besemer et al. (USPN 5,945,337 Aug. 31, 1999) in

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further view of Van Antwerp et al. (17s5,786,439 July 28, 1998).

The teachings of Cottingham et al. and Besemer et al. are described previously.

Cottingham et al. do not teach the claimed layer of water-soluble compound.

Van Antwerp et al. teach coating the surface of biosensor with uniform hydrogel (see whole doc. esp. abstract). The hydrogel may be PEG 600 (see claim 10).

One of ordinary skill in the art would have been motivated to apply Antwerp PEG-600 coatings to the combined invention of Cottingham and Besemer's chip array device in order to protect the array from interfering chemicals. Antwerp et al state that the hydrogel layer protects from interfering chemicals such as electrolytes and proteins but allows water to pass through to allow the arrays to accurately measure analyte (see column 1 lines 46-50). It would have been prima facie obvious to apply Antwerp's hydrogel to Besemer's chip device in order to allow Besemer's array to accurately measure analytes without interference from other chemicals.

8. With respect to the rejections recited above, applicant argues, in all of the 103(a) rejections, the examiner's conclusion of obviousness is based upon the improper application of Cottingham's teachings. Applicant's arguments with respect to these rejections have been considered but are moot in view of the clarification of Cottingham's teachings.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita, Ph.D. whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday thru Thursday 7:00 A.M. - 5:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571.272.0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

hgc


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

8/10/04